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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,668	09/25/2003	Richard H. Ingraham	9/213-1-C1	1467

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EXAMINER

SHAMEEM, GOLAM M

ART UNIT PAPER NUMBER

1626

DATE MAILED: 06/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/670,668	Applicant(s) INGRAHAM ET AL.	
	Examiner Golam M M Shameem	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 5, 6, 8 and 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

Claims 1-9 are pending in the application.

Receipt is acknowledged of amendment / response filed on May 19, 2004 and that has been entered.

Claims 5, 6, 8 and 9 are withdrawn from further consideration pursuant to 37 C.F.R. 1.142 (b) as being drawn to a non-elected subject matter.

Information Disclosure Statement

Receipt is acknowledged of Information Disclosure Statement (IDS), filed on 5/19/04, which has been entered in the file.

Response to Election/Restriction

In response to the restriction requirement, Applicants have elected Group I, which includes claims 1-4 and 7 drawn to a method of treating a condition caused by endothelial dysfunction with an effective amount of a compound of formula I, and also have elected the species found on top of page 35 (Remarks, page 1) of the specification with traverse is acknowledged. The traversal is on the ground(s) that all the pending claims should be rejoined and examined with the elected Group I because a search and examination of the entire Markush group can be made without "an undue burden on the Examiner".

The Examiner respectfully disagrees with the Applicants because the products of Invention groups I-III differ materially in structure and in element from each other and therefore, are capable of supporting their own patents. The invention groups I-III are related to a set of structurally diverse compounds, and their methods of use (chemical structures, which are similar, are presumed to function similarly, whereas chemical

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structures that are not similar are not presumed to function similarly), which do not possess a substantial common core wherein a reference anticipating one would not necessarily render the other obvious and to search all the above groups in a single application would be an undue burden on the Examiner. Because of the plethora of classes and subclasses in each of the Group, a separate search considerations are involved, which would impose a serious burden on the Examiner to perform a complete search of the defined areas if unrestricted. Also the fields of search are not coextensive. The wide disparity among the groups requires that many divergent fields must be searched, including all classes and subclasses of U.S. and foreign patents as well as journals and publications. Moreover, the Examiner must perform a commercial database search on the subject matter of each group in addition to a paper search, which is quite burdensome to the Examiner. For these reasons, Applicant's arguments are found unpersuasive and, therefore, the requirement for restriction and election of species is still deemed proper and is therefore made FINAL.

Applicants preserve their right to file a divisional on the non-elected subject matter.

As set forth in the restriction requirement and an election of a single compound (or set of compounds), the invention will encompass all compounds that fall within the scope of the claim is as follows:

A compound having the formula I wherein:

R₁ is as claimed,

R₂ is as claimed,

R₃ is as claimed except any "heterocyclyl" substitution,

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R₃ is as claimed except any "heterocyclyl" substitution,

L is -NHC(O)-, -NHC(O)O-, -NHC(O)C(O)-,

R₄ is as claimed, and

R₈ is as defined,

As a result of the election and the corresponding scope of the compound identified, claims 5, 6, 8 and 9 and the remaining subject matter of claims 1-4 and 7 are withdrawn from further consideration pursuant to 37 CFR 1.142 (b) as being drawn to non-elected inventions. The withdrawn subject matter of claims 5, 6, 8 and 9 is properly restricted as it differs materially in structure and in element from the elected subject matter supra so as to be patentably distinct there from.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claim in the subject matter which the applicant regards as his invention.

Claims 1-4 and 7 are rejected under 35 USC § 112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The expression "a condition caused by endothelial dysfunction", (claim 1, line 1, page 30) renders the claims indefinite because it is not clear what the applicant is intending to encompass with this expression. The above expression is not defined in the claims so as to ascertain the metes and bounds of the claimed subject matter. The expression "a condition caused by endothelial dysfunction", is an open-ended expression (because endothelial dysfunction plays a critical role in a large number of pathological conditions such as diabetes, hypertension,

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renal disease etc as indicated on page 3, lines 1-10 of the specification) that, when used within a claim, makes the claim open-ended and indefinite. The omission of failing to describe the claimed invention renders the claims incomplete. It is suggested to amend the claims with in the context and scope of the claims (limiting specific type of disease condition that actually contemplated in the specification) in order to overcome the rejection.

Objections

Claims 1-4 and 7 are objected to for containing non-elected subject matter. The claims should be amended to exclude non-elected subject matter and within the scope of elected compound.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Golam Shameem, Ph.D. whose telephone number is (571) 272-0706. The examiner can normally be reached on Monday-Thursday from 6:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane, can be reached at (571) 272-0699. The Unofficial fax phone number for this Group is (703) 308-7921. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

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Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mcKane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (571) 272-1600.



Golam M M Shameem, Ph.D.
Patent Examiner
Art Unit 1626, Group 1600
Technology Center 1

June 23, 2004